FENESTRATED ASYMMETRIC INTRACARDIAC DEVICE FOR THE COMPLETION OF TOTAL CAVOPULMONARY ANASTOMOSIS THROUGH CARDIAC CATHETERIZATION

FIELD OF THE INVENTION

The present invention relates to an intracardiac device for treatment of the following congenital heart diseases (C.D.) with univentricular physiology: ~~THE FOLLOWING TABLE SHOWS DIFFERENT CHDS THAT NEED SURGICAL TREATMENT Congenital Heart Disease with Univentricular Physiology~~

Single ventricle,

Tricuspid atresia,

Hypoplastic left heart syndrome (HLHS),

Pulmonary atresia with intact septum and hypoplasic right ventricle,

Transposition of the great vessels, with noncommitted ventricular septal defect and small right ventricle [[.]],

Double outlet right ventricle and poor anatomy,

Criss-cross heart,

Congenital right ventricular hypoplasia, and

Ebstein's malformation.

BACKGROUND OF THE INVENTION

Most of these CHDs need a ~~sequential~~ multistep treatment strategy. Some of them (such as hypoplastic left heart syndrome) require a special ~~therapeutic, whose end point is common to all~~ therapy.

When the patient is born with single ventricle (classic C.D. of this pathology) and stenosis or pulmonary atresia that hinder [[from]] pulmonary flow, in order to maintain a proper ~~oxigenation~~ oxygenation, a prompt modified Blalock-Taussig anastomosis should be performed with a prosthesis tube of 4 mm

between the subclavian artery and the homolateral pulmonary branch, usually on the left side.

If there is [[not]] no pulmonary stenosis, a banding of the pulmonary artery to narrow the lumen, to limit the flow and the pressure transmitted to the pulmonary circuit, should be performed. This prevents the development of pulmonary hypertension [[which]] that would prevent the patient from ~~advancing towards the next steps~~ being well enough to undergo further surgical treatment.

~~Fenestrated Asymmetric Intracardiac Device for the Completion of Total Cavopulmonary Anastomosis Through Cardiac Catheterization The aim of this Fenestrated Asymmetric Intracardiac Device is to complete the Total~~ A fenestrated asymmetric intracardiac device serves to do a total cavopulmonary anastomosis through cardiac catheterization. ~~Intended Use of the Fenestrated Asymmetric Intracardiac Device To be~~ More particularly such an intracardiac device is used in pediatric cardiologic ~~interventions~~ operations, more specifically to correct specific congenital heart disease in hemodynamic ~~interventions~~ operations.

~~Former State of the Art-Physiology and Univentricular Therapeutics~~

There are different congenital heart diseases (C.D.) with only one working ventricle available, so this disability ~~forces to design~~ necessitates a therapeutic strategy which allows ~~to develop~~ the development of a special hemodynamic model. These cases are present in newborns with this cardiac malformation and it is absolutely necessary to correct it by means of surgery.

During the last decades different techniques have been introduced for the ~~sequential~~ multistep preparation of the

circulatory system, with the final aim of connecting the venous blood that comes from the heart through the superior and inferior vena cava with the pulmonary circuit, allowing [[the]] oxygenation of blood. This involves performing a bypass to the right ventricle, because the non-existence or rudimentary structure of this C.D. does not allow one to perform its ~~force~~ pump function ~~towards~~ of pulmonary circulation.

The ~~target~~ goal is to maintain [[the]] blood flow through a minor circuit with the pumping function of the only active ventricle. This circuit should have [[a]] low resistance to [[the]] flow, without obstruction sites, so that blood can flow properly, even if it is [[not]] pumped with [["]] unnatural right heart venous pathways [["]].

Under any of the two conditions described above, at the age of 6 or 8 months, patients should be subjected to a Bidirectional Glenn procedure. This procedure consists of the separation of the superior vena cava (SVC) from the right atrium (RA) and its connection with the right pulmonary branch (RPB). [[In]] This way all the venous flow of the superior half of the body will flow directly to the pulmonary artery (PA) to become oxygenated without ~~coming into~~ passing through the heart. This procedure is performed at this age because the head and the superior half of the body represent the 55% of the venous return. This is an open-heart procedure with cardiopulmonary bypass (CB).

The last step is to complete the total cavopulmonary connection (TCPC) at the age of 3 or 4 years old, by ~~carrying~~ connecting the inferior vena cava [[flow]] to the pulmonary artery, also under cardiopulmonary bypass (CB) [[too]]. The surgical techniques have been substantially modified in the last decades, specially in this phase. Since the early

Fontan-Kreutzer procedure, which consisted of joining the right atrium to the right pulmonary branch (atriopulmonary anastomosis) up to the current anastomosis with extracardiac tube between SVC and PA, several techniques have been tried.

This last-mentioned technique consists of the [[IVC]] anastomosis of the inferior vena cava (IVC) to the right pulmonary branch (RPB) with the interposition of a Gore-Tex™ extracardiac prosthesis tube with a fenestration or hole in the RA as "discharge" in order to secure the postoperative cardiac output.

At this phase, the so-called ~~"Total Cavopulmonary Connection"~~ "total cavopulmonary connection" (TCPC) is finished. ~~Lately~~ Of late, some attempts have been made [[by]] using a covered stent with a ~~interventional~~ surgical catheterization to finish this last phase, and so avoid a new surgery, simplify the technique, minimize the risks as well as [[the]] side effects [[of EC]].

These stents have an expandable tubular mesh made of different materials, such as a platinum-iridium, nickel-titanium, stainless-steel mesh and covered with an impermeable polymer, like expanded polytetrafluorothyelene (PTFE). With these devices, after performing the Bidirectional [[Gleen]] Glenn procedure, IVC is connected to SVC. ~~As well TCPA~~ The TCPC procedure with extracardiac tube as well as the procedure with the current stents have the inconvenience of supplying an unbalanced flow to the pulmonary circulation. Current stents have one or several fenestrations which allow [[the "]] discharge [["]] of blood from the circuit, if the hemodynamic condition is not ~~the best~~ ideal, allowing a right to left shunt at atrial level, so as to maintain the postoperative cardiac output. These

openings or holes need to be closed or sealed when the patient's hemodynamic condition allows one to do so.

To show a better reference frame of the former state of the art, before this invention, FIG. 1 shows schematically a heart which suffers from these CHDs, before the Glenn procedure, and in [[the]] FIG. 2 this same heart after the Glenn procedure.

The following acronyms are used in both figures:

RPA Right pulmonary artery

LPA Left pulmonary artery

SVC Superior vena cava

IVC Inferior vena cava

SHV Hepatic vein

Ra Right appendage

RA Right atrium

TV Tricuspid valve

The following are bibliographical references of these known more recent techniques:

"Surgical Preconditioning and Completion of Total Cavopulmonary Connection by Interventional Cardiac Catheterization: A New Concept," (Heart 1996; 75: 403-409).

Through this technique the field to complete by catheterization the total cavopulmonary connection of high risk patients is carried out during the Glenn procedure.

A left banding is done between RA and SVC, setting a Gore-Tex™ tube with 3 [[up]] to 7 perforations (multifenestrated) inside RA. During the next intervention, the banding is dilated with or without a Palmaz stent between SVC-AD, and the fenestrations are closed with Rashkind devices of 17 mm, used for the closure of the patent ductus arteriosus. If it is not

possible to perform this technique, a covered stent inside a Gore-Tex™ tube is ~~placed~~ installed.

"A Novel Technique for Establishing Total Cavopulmonary Connection: From Surgical Preconditioning to Intervention Completion," (J. Thorc Cardiovasc Surg. 2000; 120; 1007-9).

This technique contemplates the experimental ~~settlement~~ use of a cavo-caval anastomosis with a covered stent through cardiac catheterization. Previously, a side-to-end anastomosis between SVC and distal RPB with PTFE should be performed. SVC is left ~~banding~~ banded in its joint with RA. The next procedure is to introduce [[, via]] endovascularly [[,]] a stent graft from the right internal jugular vein, ~~placing~~ fitting it through the SVC banding, between SVC-RPA joint and IVC over the hepatic vena end. Then the pulmonary cava-cava artery anastomosis is completed.

"Effect of Baffle Fenestration on Outcome of the Modified Fontan Operation," (Circulation 1992; 86:1762-1769).

This technique shows the benefits of fenestration in the Fontan procedure in patients [[of]] at high risk. This [[Study]] study compares a group of 91 patients in which a fenestration of 4 mm has been left in the intracardiac tube with 56 patients without fenestration. It was concluded that the fenestrated tube is associated with [[a]] low mortality, less incidence of pleural effusion and less days in hospital.

Up to today none of these ~~interventions have~~ operation has shown optimal outcomes because in the long term a number of patients need different ~~interventions~~ operations.

From the age of 6 approximately, the percentage of systemic venous return, which is kept up to the adult age, is reached. The 35% of the pulmonary flow of a healthy adult

without C.D. is supplied by SVC and the 65% by IVC. The right lung, anatomically bigger, should receive approximately 55% of blood and the left lung, smaller, 45%. This implies a flow division from the IVC in 20% of the total (30.7% flow from IVC) that should run to the RPA, while the 45% left runs to the LPA.

With the C.D. corrective techniques currently known, it is not always feasible to guarantee a proper division of the pulmonary blood flow, resulting in a deficient supply according to the technique used in one or the other lung, usually the left one.

Another problem of the known corrective techniques [[arid]] with the devices ~~of the CHDs~~ mentioned above and which can result in serious inconveniences is the IVC ~~transversal~~ transverse section in the grown up children which has an average of 18-20 mm, while the PA has an average diameter of 10-13 mm approximately. The known techniques and devices resolve this problem by connecting with a suture the ~~superior extreme~~ upper end of the extracardiac conduit to the PA, and ~~crushing~~ flattening it, which transforms a theoretically round section into a theoretically elliptical ~~transversal~~ transverse section, resulting in an area decrease, and so increasing the flow resistance, if the speed of blood flow is reasonably constant.

The last problem is the longitudinal dimensions in case the device is intracardiac, because not all the patient's anatomies have the same dimensions and so the device should be adapted to the somatic growth.

OBJECT OF THIS INVENTION

The main target of this invention is to ~~obtain~~ provided a covered stent or endoprostheses device to complete the total

cavopulmonar connection or anastomosis through a cardiac catheterization procedure.

This device should be implanted in procedures performed in those CHDs which need univentricular correction. Previously, an anatomical preparation during the Bidirectional Glenn procedure should be done.

An intracardiac device is another [[aim]] object of this invention, which allows a best distribution of the blood flow dynamics, being able to [[lead]] feed between 30 to 35% of the blood flow from the IVC to the RPA and between 65 to 70% of the blood flow to the LPA, establishing a physiological distribution of the blood flow in both lungs, which the previous Bidirectional Glenn procedure brings to the right lung.

~~One of the aims~~ Yet another object of this invention is a ~~device of~~ covered stent or endoprostheses [[type]] which allows one to stop the blood flow from the pulmonary artery trunk (in the case of banding of it) or to close the Blalock-Taussig anastomosis (in stenosis or pulmonary atresia cases).

Another [[aim]] object of this invention is an intracardiac device whose ~~transversal~~ transverse sections allow to compensate the shape change (flattening of the ~~transversal~~ transverse section) and to obtain a reasonable constant ~~transversal~~ transverse section.

~~The aim~~ Yet another object is an intracardiac device invention which allows adaptation and compensation of the existing dimensional differences in the RA in different patients.

~~The aim~~ Yet another object is ~~the invention of~~ a device which allows ~~to conduct the~~ blood to be fed from the IVC to the pulmonary artery ~~in its join~~ where it joins with the trunk and the pulmonary right branch.

~~The aim~~ Yet another object is ~~the invention of~~ a device which allows to discharge the blood from the fenestration towards the RA in non ideal cases ("high risk patients").

~~The aim~~ Yet another object is ~~the invention of~~ a device which allows the physiological distribution of the pulmonary flow matched with the Bidirectional Glenn procedure, improving the existing models.

~~The aim~~ Yet another object is ~~the invention of~~ a device which allows the treatment of the pulmonary tree distortion, decreasing the total resistance.

~~The aim~~ Yet another object is ~~the invention of~~ a device is to set a blood flow with the smallest power losses with regards to the existing one.

~~The aim~~ Yet another object is ~~the invention of~~ a device is to contemplate the heart somatic growth by its left convexity curvature and the re-expansion of its diameters.

And, the final [[aim]] object is ~~the invention of~~ a device to ~~derive~~ draw the blood from the liver (IVC) towards both lungs, which is a physiological important circumstance which avoids the development of pulmonary arteriovenous fistulas.

~~BRIEF DESCRIPTION~~ SUMMARY OF THE INVENTION

The ~~Fenestrated Asymmetric Intracardiac Device~~ fenestrated asymmetric intracardiac device for the completion of total cavopulmonary connection through cardiac catheterization is characterized ~~for having~~ in that it has a bifurcated tubular ~~conduct~~ conduit, whose parts are: a first ~~inferior~~ lower portion and a second ~~superior~~ upper portion ~~, being~~ both ~~portions, one after another, in accordance with the same axis which is warped in the space of the unique conduit~~ centered on a curved or warped line or axis.

The first portion is a tubular mesh covered with an impermeable polymer with a curvature of between 35° and 45°, ~~having~~ this first portion having in its ~~inferior~~ lower end [[,]] a substantially circular cross-sectional shape ~~transversal section, substantially circular,~~ with a diameter between 16-20 mm, while in its ~~superior~~ upper end the first portion has a ~~transversal section,~~ cross-sectional shape that is progressively flattened going upward ~~and with a~~ so as to be substantially oval ~~shape,~~ while being ~~the transversal sections along the axis of the same area~~ of uniform cross-sectional size or flow cross section along its length.

The ~~lateral~~ side of this first portion ~~presents at least~~ is formed with a hole or fenestration ~~which is selectively closure and which~~ that can be closed and that connects the interior of this conduit with the exterior. The ~~inferior~~ lower end of this first portion can ~~present~~ be formed by a mesh structure without polymeric cover, defining a ~~n end of~~ permeable conduit end. [[,]] This first ~~inferior~~ lower portion is followed by the second ~~superior~~ upper portion which has a tubular mesh covered, at least in some parts, by an impermeable polymeric material and with ~~transversal sections, along the warped axis, being~~ a cross-sectional shape that is ever more oval going upward to ~~get a smaller diameter of the ellipse,~~ to end with an elliptical shape having a minor diameter between 10-13 mm.

Both ~~transversal~~ transverse sections are substantially of the same area. After ~~getting~~ the second portion ~~of this section whose~~ reaches a diameter [[is]] smaller than 10-13 mm, it bifurcates into two branches, one of the branches being longer and ~~the transversal sections~~ of circular cross-sectional shape with a diameter between 10-13 mm and prolonging the warped axis with a posterior inclination, while the other branch is ~~projected after the shape of~~ formed as a short ~~appendix of a transversal section~~ obliquely backwardly diverging extension of substantially circular section with a diameter of 10-13 mm and ~~obliquely divergent and backwards~~ forming with ~~respect to~~ the ~~longest~~ long branch a deformed "Y". ~~; being the~~ The conduit having an overall length of ~~the first portion~~ between 60-75 mm, [[while]] with the longer branch ~~of the second portion is~~ being between 18-25 mm long, and the ~~length of the~~ short ~~bifurcated axis is~~ branch being between 4-8 mm long and having ~~defining the short appendix in its bifurcation with respect to the longer longest branch with~~ a wall portion ~~which faces~~ that intercepts between 50%-70% of [[the]] blood flowing up ~~that runs~~ through the main tubular ~~conduct~~ conduit from its ~~inferior~~ lower end. The ~~inferior~~ lower end of the first section defines a connection between the ~~inferior~~ lower vena cava and the hepatic venous, [[being]] with this tubular ~~conduct~~ conduit lodged inside the right atrium and anchored in the joint of this structure and the IVC, while the ~~longest section~~ long branch is lodged inside the left pulmonary artery ~~stating a relation of~~ in close contact with the internal walls thereof and ~~determining~~ forming an obstruction of the pulmonary artery trunk, while the short branch ~~of the short length bifurcation~~ is lodged inside the source of the right pulmonary artery. ~~PREFERRED EXAMPLES TO PERFORM THIS INVENTION~~

BRIEF DESCRIPTION OF THE DRAWING

The following ~~sketches~~ drawing figures together with their description will illustrate ~~the examples of the performance of~~ this invention. This ~~example of performance~~ illustrated embodiment should be understood as one of the many possible constructions of the invention, not limiting its use, including ~~in its protection boundary the~~ possible equivalent means described, [[being]] the ~~spectrum~~ scope of this invention being determined by the [[first]] claims ~~attached in the Claims Chapter~~. Likewise, in this figures, the same references identify the same or equivalent means.

FIG. 1 [[,]] shows schematically a heart ~~portion~~ with [[the]] congenital C.D. ~~, depicted~~ as described above and ~~presents only the influence~~ showing only the area related to RA.

FIG. 2 [[,]] shows the same heart portion [[of]] as FIG. 1 which has undergone the Glenn procedure and banding in the pulmonary artery.

FIG. 3 [[,]] shows a view in lateral elevation of one of the possible constructions of the invention ~~device~~.

FIG. 4 [[,]] shows a ~~construction~~ detail of the device in ~~detail~~ section.

FIG. 5 [[,]] shows the same device turned 90% around its axis.

FIG. 6 [[,]] shows schematically the cross-sectional areas, ~~relation in the transversal section with the projection of determined sections and~~ illustrating the concept of the division of the blood flow which runs up in IVC in the device ~~bifurcation~~.

FIG. 7 [[,]] shows the ~~invention~~ device lodged inside the FIG. 2 heart.

FIG. 8, shows the section taken along line AA [[cut]] of FIG. 3, and [[,]]

FIG. 9 [[,]] shows the section taken along line BB [[cut]] of FIG. 3.

SPECIFIC DESCRIPTION

FIG. 1 shows schematically a RA of a heart with a characteristic congenital heart disease in its ~~previous~~ condition [[,]] before a Glenn procedure.

FIG. 2 shows the same RA after the Glenn procedure, which consists of the sectioning of SVC, suturing the ~~superior~~ upper section [[1SVC]] SVC1 to the RPA branch ~~, joining~~ to join them at s1, while ~~2SVC, which~~ SVC2 is connected to RPA is ~~sutured and~~ closed [[with]] at s2 with sutures. ~~Before a banding has been practiced in~~ Previously the pulmonary artery has been banded at b.

With this ~~intervention~~ operation the heart is ready for the next ~~interventions~~ operations described above ~~depicted~~. The invention contemplates an asymmetric intracardiac device which ~~defines~~ is a covered stent or endoprostheses ~~form by~~ having a first ~~inferior~~ lower section (1) and a second ~~superior~~ upper section (2). Both sections (1,2) are ~~one after the other according to the same~~ aligned on a common warped axis X-X ~~prepared in the same space forming a unique~~ and form a single tubular conduit.

The first ~~inferior~~ lower section (1) is a mesh, like a stent mesh, that is to say a mesh made of metallic threads joined or welded and covered with an impermeable polymeric material, such as polytetrafluorothyelene (PTFE). The ~~inferior~~ lower end or section (1a) of the ~~inferior~~ lower portion (1) is preferably not covered and is inserted inside the IVC, allowing the mesh

portion without cover to collect [[the]] blood which comes from the [[VSH]] SHV.

There can be two different ~~completions with respect to the constitution of~~ parts that form these two sections (1,2). In one ~~of these constructions~~ embodiment the ~~inferior~~ lower section (1) is axially inserted inside the second section (2), the joining area is shown in reference (3) and FIG. 4 shows this in detail. This construction allows the ~~Interventional Cardiologist~~ interventional cardiologist to make a telescopic adjustment of the device's total length and to ~~adequate~~ adapt it to the anatomy of each patient, moving section (1b) which is inserted inside the ~~inferior~~ lower end [[(2a)]] of the ~~superior~~ upper portion (2)

The other possible completion is the one in which the ~~inferior~~ lower section (1) is ~~followed by~~ unitary the ~~superior~~ upper section (2), forming only one piece.

From the material point of view, this device can be formed by [[a]] the same mesh in both sections (1,2) or the ~~inferior~~ lower portion (1) can be made of a more rigid mesh, while the ~~superior~~ upper portion (2) can be made of a more flexible and soft mesh. [[So]] Thus it is important ~~to say~~ that the device of the invention can present a unique mesh of equal resistance along the device, or a mesh with different rigidity and elasticity.

The first portion (1) ~~includes~~ has a curvature between 35°-45°, ~~having~~ the first section having in its ~~inferior~~ lower end (1a) a ~~transversal~~ transverse section that is substantially circular with a diameter between 16-20 mm, which is shown in FIG. 8 ~~, where it can be seen the AA cut of FIG. 3~~, while in its ~~superior~~ upper end this first section presents a ~~transversal~~ transverse section that is progressively flattened and [[with]]

that has a substantially oval shape, which is shown in FIG. 9 and ~~showed by BB cut~~ in FIG. 3.

One of the important characteristics of this invention in one of its preferred constructions is that the ~~transversal~~ transverse sections along the XX axis [[which]] have substantially the same area from the ~~inferior~~ lower end (1a) ~~until it gets~~ up to an area (4) ~~bellow~~ below the bifurcation described in more detail below because ~~, precisely, having to join~~ in this zone ~~, when~~ the device has to fit with the pulmonary artery [[joins]] and with the RPA ~~branch,~~ whose average diameter is 12 mm, so that it must have an oval or elliptic section whose smallest diameter according to the Y axis of FIG. 9 is equivalent to 12 mm, which allows ~~to rest the biggest axis~~ it to fit the bigger dimensions of the RPA, and ~~so manage to~~ and thereby maintain a ~~transversal~~ transverse section with the same area.

The ~~lateral~~ side wall of this first section (1) ~~presents~~ is formed at least [[a]] one hole or fenestration (5) of 4 mm [[of]] diameter, ~~with selective closing,~~ which can be closed and which allows ~~communicates~~ the conduit interior to communicate with the exterior [[of it]].

After reaching this second section (2) ~~a high equivalent to~~ at the section (4) in FIG. 3, this second section (2) bifurcates in two branches. One of these branches is longer, ~~and with transversal~~ has a transverse sectional size which [[are]] is substantially circular with a diameter between 10-13 mm, and ~~following~~ follows the warped axis XX ~~, indicated in reference~~ as shown at (6), ~~introducing it in a tight-fitting way~~ so that it can fit snugly inside the LPA, establishing [[an]] a hermetic tight relation with [[the]] its internal walls, and closing the pulmonary artery entrance.

The other branch (7) is projected in the shape of a short ~~appendix~~ extension of ~~transversal~~ substantially circular transverse section ~~s, substantially circular,~~ with a diameter of 10-13 mm and obliquely ~~divergent with~~ diverging toward the posterior ~~inclination~~, forming with respect to the branch (6) of major length [[,]] a distorted Y. ~~, inserting~~ This short branch (7) fits into the beginning of the RPA.

In the device the first section (1) length is between 60-75 mm while the major length branch (6) of the second section is between 18-25 mm [[long]], and the length of the short bifurcated ~~appendix~~ extension (7) is between 4-8 mm.

Another important aspect of this invention is that it provides a distribution of the RPA and LPA flows balanced according to the physiological model. ~~For these~~ To do this according to the invention ~~ponders that~~ the branch of major length (6) should be the followed by of the warped axis XX, but from this bifurcation the ~~transversal~~ transverse section (6) is substantially circular with a diameter ~~that oscillates around~~ about 12 mm. ~~Originated in~~ Starting from an elliptic tubular ~~conduct~~ conduit [[in]](4) with an area equivalent to a circle with an average diameter of 18 mm, the ~~transversal~~ transverse area (6) is notably smaller than the ~~transversal~~ transverse section (2) in zone (4), so the short ~~appendix~~ extension (7) which ~~is born~~ starts in this area (4) ~~is projected from the transversal~~ with a cross-sectional size or transverse area equivalent ~~with a circumference~~ to a circle of a ~~n average~~ diameter of about 18 mm. The transition between these two ~~transversal~~ transverse areas is ~~surpassed preparing the appendix (7) of~~ at the extension wall (8) that is substantially

perpendicular to the blood flow which runs through (1,2), forcing part of the flow to divert through (7) when it collides with (8).

In another words, the short ~~appendix~~ extension (7) in its bifurcation with respect to the branch of major length (6) defines a wall portion (8) which [[faces]] blocks between 50%-70% of the ~~projected one, which runs through the~~ blood flow, which runs up in the tubular conduit (1,2) from the ~~inferior~~ lower end, as indicated by the arrows in FIGS. 3 and 6. This short ~~appendix~~ extension can be covered, or can be a mesh without a coating.

In another construction of the invention, ~~is contemplated~~ the branch (6) of the bifurcation [[which]] has a ~~transversal~~ transverse section slightly ~~decreased~~ decreasing to its free end, with the aim of being applied in cases in which it is necessary to limit in a small ~~average~~ amount the blood volume towards LPA, and to increase the flow towards RPA, according to the Interventional Cardiologist's criterion.

FIG. 5 shows the device of FIG. 3, projected with a lateral elevation from its left side. It is emphasized that the XX axis is warped in [[the]] space, and the end (9) of the branch (6) runs backwards like the branch (7). It can also be seen [[, too]] in this figure that the ~~transversal~~ transverse sections of section (2) are flattened [[up]] to gain a smaller diameter compatible with LPA diameter.

FIG. 6 is an idealization which shows the area relationships between the different device branches, showing the sections which form a slight lateral perspective, as if they [[have]] had straight axes and constant and circular ~~transversal~~ transverse section.

This situation ~~allows to establish that~~ shows the XX axis [[is]] aligned with section (6) of the bifurcation, which is moved towards a lateral of the device, while the branch (7) of the same bifurcation is aligned with another [[MM]] axis. These two axes represent the blood flows ~~separation and flowing~~ that separate and move through (6) and (7). In the bifurcation quoted above, it is important to stress that the portion (2) [[shows]] has a ~~transversal~~ transverse area (10) ~~, belonging the transversal~~ joining the transverse areas (11) and (12) [[to]] of sections (6) and (7). It can be seen that areas (11, 12) are smaller in magnitude that area (10), in a proportion substantially coincident with the flow rate, which derives from branches (6) or (7).

~~Discussion about Technique Application of the Current Invention~~ FIG. 7 shows the device of the invention placed inside RA, according to one of the several possible techniques, not being either ~~this technique neither~~ unique nor exclusive. This technique ~~in attaching~~ attaches the appendage end (Ra) with the pulmonary trunk neck with the RPA ~~orientated~~ oriented towards the LPA. This attachment can be made by suturing the appendage end and then making a puncture from inside the RA ~~so that to give way to~~ accommodate the device bifurcation (6,7) or suturing a short ~~conduct~~ conduit (Con) connecting the Ra with the RPA, puncturing or cutting and passing the device ~~section~~ through that ~~conduct~~ conduit (See FIG. 7).

The connection site is the joint, established beforehand by surgery, between the right appendage (Ra) and the right pulmonary artery (RPA) close to the pulmonary trunk.

This connection avoids the sinus node and the complication caused by conduction disorders. The surgery

technique, during the previous Glenn procedure, should contemplate a reinforcement with Gore-Tex™ through an anastomosis of both anatomical references and attaching the surface of the ~~superior~~ upper right appendage with the ~~inferior~~ lower one of the proximal right branch. The "floor" of the right branch will open freely and the appendage "vault" will divide into cross sections with an elliptic area and then these incisions should be sutured ~~leaving in its central section a radiopaque gost~~.

In its unified version, the device is autoexpandable, it releases when [[the]] an installation sheath is withdrawn, when the device is deployed from its distal end [[(API)]]. It will be installed according to the anatomical features, up to the bifurcation site. The deployment device arm mechanism [[(7)]] or the right branch of the bifurcation [[is]] assumes the illustrated shape by elastic recovery of its shape and orientation. This happens because it is perpendicularly telescoped inside the device tubular body. The primary anchorage is caused when both branches are ~~intubated~~ fitted in the installation sheath. The secondary anchorage is at IVC level.

~~In its version of two bodies~~ When made of two parts (FIG. 4), the distal or ~~superior~~ upper portion (2) is autoexpandable and is inserted in the pulmonary branches, as depicted above. The ~~inferior~~ lower or proximal section (1), the one that [[have]] has the fenestration, can be made of a more rigid material, or with a less flexible material, and can be deployed with a balloon, by inserting it inside the ~~superior~~ upper portion (2).